EXHIBIT E

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
SHIRLEY FREEMAN, et al. v. ETHICON, INC., et al.	CIVIL ACTION FILE No. 2:12-CV-00490
SHIRLEY WALKER, et al. v. ETHICON, INC., et al.	CIVIL ACTION FILE No. 2:12-CV-00873
WILSON WOLFE, et al. v. ETHICON, INC., et al.	CIVIL ACTION FILE No. 2:12-CV-01286

Deposition of ROBERT BRIAN RAYBON, M.D., taken on behalf of the Defendants, pursuant to the stipulations agreed to herein, before Maxyne Bursky, Registered Professional Reporter, at 440 College Avenue, Athens, Georgia, on the 18th day of April, 2016, commencing at the hour of 8:51 a.m.

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ROBERT BRIAN RAYBON, M.D.,
having been first duly sworn, testifies as follows:
EXAMINATION
BY MR. KOOPMANN:

Q. Good morning.

A. Good morning.

Q. Please state your full name for the record, please.

A. Robert Brian Raybon.

Q. Good morning, Dr. Raybon. We met briefly off the record, but again for the record, my name is Barry Koopmann and I am one of the attorneys representing Johnson & Johnson/Ethicon in this litigation.

You understand we are here today to take your deposition regarding the Prolift device for the Wilson Wolfe case and the Prolift+M device for the Friedman and Walker cases?

A. Yes, sir.

Q. You have been deposed several times before; is that correct?

A. That's correct.

Q. So you are generally familiar with the process?

Prolift instructions for use or IFU?

A. That would have been when that, as I said, that rep came around back in that time. As I said, I'm pretty confident he came by before I went to this cadaver lab and so I think he gave me an IFU or some other product information as well as a DVD or CD to review.

Q. Do you remember who that rep was?

A. Yes, his name was Marquel, M-A-R-Q-U-E-L, Fleetwood, just like the Cadillac.

Q. Do you think that was also the first time you read a Prolift brochure, when Mr. Fleetwood gave you some product information?

A. I'm pretty confident that was. Remember at that time, this stuff was just getting going, I mean, literally, I can't swear to this, but I don't think Prolift had been out on the market in Georgia, or nationally, for that matter, that long. I think it, put it to you this way: He told me years later that, I think I did the first Prolift in Georgia there.

Q. So is it fair for me to understand that the first time you ever heard of the Prolift device was when Mr. Fleetwood mentioned it to you and then

you learned how to implant it at the cadaver lab?

A. Yes, sir, and I had reviewed the materials he had given me as well.

Q. I think you indicated in your Rule 26 report that you used a Prolift device about 25 times; is that correct?

A. Correct.

Q. Was it 25 times exactly or about there?

A. I tried to go on the low end. I feel it was probably higher than that but I want to -- I definitely feel confident with 25.

Q. Over what time span did you use those 25 Prolift devices?

A. At that time, I was doing about, it ranged from 100 to about 100 -- I remember my high point there was 130 vaginal repairs there in a year. And so I'm pretty confident it was over the course of the next six months, whenever I started that.

And maybe even less, because I was, I mean, very, very, very busy during that time and I was, I would kind of, you know, I was doing Avaulta at the same time. And because at that time, my thinking was, certainly maybe Avaulta, maybe Bard doesn't have a lock on the best way to do this. I

mean, I should at least explore something else and I did get trained on it and had reviewed everything. So that's why I chose Prolift.

If I hadn't been, I probably, it would have been a toss-up at that point that I did Apogee or Perigee or Prolift and I probably at that point would have had to go to training to do one of those two.

Q. So after you left the cadaver lab, was it the case that the Avaulta was not on the market so you couldn't go back and start using that again?

A. It was just getting ready to get released, like literally within a month or two of that lab because I did the first one of those in the world when it came out commercially.

Obviously, I did not, Jim Ross did the, a lot of the initial work, but before it was commercially available, that's what they would say, when I would teach at these conferences or whatever, they would say, Raybon did the first commercially available Avaulta in the world. So it was pretty soon after that.

Q. Were there aspects of the Prolift device or the procedure to implant the Prolift device that

A. Anywhere in the body, you mean abdominal or vaginal?

Q. Yes.

A. Oh, yes. I mean, any surgeon has had a wound dehiscence, positively.

Q. Would you agree that there are a lot of doctors in the United States who believe that Prolift was safe and effective based on the published data?

A. I would say that there are a pretty good number that felt like it was safe.

Q. And you disagree with those doctors?

A. I disagree with those doctors.

Q. When the Prolift device was introduced, that wasn't the first time surgeons implanted mesh transvaginally, correct?

A. Correct. If I remember correctly, I believe there were some attempts back in the 80s, late 80s with some different materials and I don't think it ended up very well.

Q. When was the first time you ever heard of the Prolift+M device?

A. I think it was several years after I had stopped doing Prolift and I believe the rep at that

time who was not Mr. Fleetwood, I cannot remember the fellow's name, came by and detailed me on it and brought lunch there. I think in Georgia, because of the volume of procedures and how busy I was, I think I had a target on my back, not just for Prolift but any of the manufacturers that had Prolift procedures -- excuse me, prolapse procedures. And so, even though I had stopped using it, I tried to be informed of what was out there just so I would at least know.

And I think that was the, I'm pretty sure that was the first time or, of course, I could have seen it in a journal there, an advertisement there perhaps.

Q. You have never used the Prolift device in any of your patients, correct? Prolift+M device -- strike that. Let me start over.

A. Okay.

Q. You never used the Prolift+M device in any of your patients, correct?

A. I did not.

Q. Did you ever study the Prolift+M in a clinical research setting?

A. No, I did not.

Q. Would you agree that in some patients, the use of Prolift+M was very efficacious?

A. To be honest with you, I think that you can say that, just like what you said before, there are some people with vaginal mesh, transvaginal mesh implantation that have done okay. And I wouldn't change that for Prolift+M, I wouldn't lump them all in one basket, but there are some that thankfully have done well.

Q. So you would also agree that there are some patients who have had a Prolift+M implanted who have had no complications?

A. I would say there are some, yes.

Q. And there are patients who have had a good experience with the Prolift+M device?

A. I suspect there are, yes, sir.

Q. What do you think the rate of mesh exposure is with the Prolift+M?

A. I don't think that it is any different.

Q. As the Prolift?

A. Correct, because I have definitely, I have removed quite a number of Prolift products, some of which have been Prolift and some of which have been Prolift+M and I didn't get a feel that in those that

have but I think now being a little wiser in the ways of the world, in the last eight to ten years, yes. I do a lot of up to date searches on a lot of things just to make sure I remain up to date in my thinking.

Q. Is it fair to say that the primary means by which you obtain information about short-term or long-term risks that you counsel your patients about is from your review of medical textbooks, peer-reviewed literature, your education, your training, your discussions with other surgeons and your clinical experience?

A. I think so. I think these days, textbooks are becoming close to the bottom of the list. By the time they are published, they are out of date.

Q. Is it fair to say that you don't rely on medical device manufacturers to tell you how to practice medicine?

A. Absolutely not. I do not rely on that.

Q. You certainly don't rely on a medical device manufacturer to tell you how to counsel your individual patients on the risks and benefits of the procedures that may or may not be appropriate for that particular patient, correct?

A. I agree with that. I think the medical device manufacturer's role is to be another item on that list that you just mentioned a while ago that I consult. They can be a useful information person that can get information for you and so forth. But you shouldn't rely just on that alone.

Q. There was not a single transvaginal mesh product to treat prolapse for which there were more clinical studies published in the medical literature for Prolift, correct?

A. Say that one more time.

Q. There was not a single transvaginal mesh product to treat prolapse for which there were more clinical studies published in the medical literature than Prolift, correct?

A. I think you may be right on that, yes. I think that is correct.

Q. There are more medical studies done to evaluate the safety and efficacy of Prolift than there were for any other transvaginal mesh medical device used to treat prolapse, correct?

A. I would agree that there's more in the literature on Prolift. I don't necessarily know about the medical and safety, that there's more on

that in there.

Just with the transvaginal mesh things we talked about, the Cochran review, a lot of the questions, one of the things you just asked, the literature there was very low to low quality. So I don't know that there's great quality on that.

Q. Other than Prolift, Gynemesh PS was the most studied transvaginal mesh product to treat pelvic organ prolapse, correct?

A. I think it definitely hit the ground, it was one of the first ones on the ground. By that very fact, there's more information that you suggest out there.

Q. Are you aware of any valid scientific evidence or data stating that there is another mesh material in the world that is safer and more effective for treating pelvic organ prolapse than polypropylene?

A. I think from reviewing Ethicon's internal documents, I think that they had come up with one they felt.

Q. What was that?

A. The PVDF that you mentioned, or what was their term going to be for it, ProNova.

Q. Did you consider those internal company documents that you are referencing that in turn reference PVDF or ProNova to be valid scientific evidence or data?

A. I think that a company such as Johnson/Ethicon has a lot of assets at their disposal to look into such things, and I think that certainly some of their key people really felt like it had a lot of potential benefits there. But when you asked me about reviewing internal documents, I didn't have access to those until this litigation. So before the litigation, I wouldn't have had any idea.

Q. Are you aware of any peer-reviewed published data stating that there is another mesh material in the world that is safer and more effective for treating pelvic organ prolapse than polypropylene?

A. I don't know of one right off the top of my head.

Q. What are the risk factors that can lead to a mesh exposure in a patient?

A. I think there are many that fall under different categories. Obviously, one is going to be

surgeon's technique. You have to mention that.

Number two, what the patient brings to the table. Does she have medical issues that would compromise wound healing? Is she going to be a compliant patient? There's many things there.

Then you have to figure the properties of the mesh itself. I think I have become fond of quoting in the last several years, right mesh, right patient, right surgeon. And for the outcome to be the best, you have to have all three.

Q. Sometimes mesh exposures are asymptomatic, correct?

A. That's correct.

Q. Meaning the patient isn't experiencing any symptoms from it?

A. Correct. She may come in and not even know she has it until she has her annual exam.

Q. Do you believe that the safer alternative design to Prolift is a native tissue repair?

A. I think if you are talking about vaginal prolapse repairs, I think that if you are talking about safety and the potential for extensive morbidity, then a native tissue repair wins hands down when we are looking just at that.

Q. Do you have an alternative design for the Prolift or Prolift+M devices that you think would have made them safer?

A. I think that the obturator approach, looking backwards, shouldn't have been done there. I think the arm meshes lent itself to asymmetric scarring and contracture which producing a lot of the pain and discomfort and dyspareunia that we see today. So the first thing is I wouldn't do an arm mesh, number one.

They were looking at this anyway as part of their next generation of a tissue that was designed specifically for the pelvic floor. That was one of the things we were looking at, is doing away with the arms or making the arms absorbable where the arms would no longer exist.

I think that's an interesting concept, arms that don't last or go away. But I think, number one, it has to not go through the obturator. Number two, I think what would need to be used is the absolute best material that's available, drawing upon experts that have studied this, that have studied degradation of polypropylene in the body for many, many years. And then the last thing is

really, really invest in the education of the surgeons.

Q. Are there any other aspects of the design of the Prolift or Prolift+M devices that you think could be made safer?

A. I think those are the big things. I think you get rid of the trocar-based transobturator passes. You put a lot of time and effort into your surgeon training and make sure that they are adequately training and are comfortable, and then use the best material possible. I think those are the big three.

I think some of the other stuff like shape of the mesh, those type dimensions are, you are never going to please every surgeon. I think those are not as important there.

Q. Have you done any testing or experiments to investigate the feasibility or the safety of mesh devices using these alternative design features that you just described?

A. We get some stuff, not with Prolift, no, but I did some stuff similar to what you are asking with Bard there where there was a few cadaver courses, quote, a few cadaver sessions where I was

the only physician in attendance. I was there with, I remember one specifically where it was myself, some support staff and a Ph.D. anatomist, from I think it was UT, that was present.

We were looking at some designs some of which I had some input into, some I did not. And I have no knowledge if any of those ever went anywhere.

Q. Was that sort of a round table discussion where they would bounce ideas off you and see what you thought about them or was it testing where you actually did some sort of action on these things?

A. Yes, both. I would say that some of the round table stuff was done perhaps at separate sittings where it was me as well as multiple other physicians giving their ideas on things, and then I happened to be chosen for whatever reason for a couple of sessions where I was the only action person; so that in other words, there were several cadavers.

I would put some of their ideas into action, if you will, and then the anatomist would do cutdowns to figure out what I had just done.

Q. Have you ever created a pelvic organ

prolapse mesh device with this design that you just described where it did not incorporate the obturator approach with trocars, it had no arms, and utilized the best mesh available?

A. I have not.

Q. When you said the alternative design that you would advocate for the Prolift or Prolift+M devices would incorporate the best material available, what material is that?

A. I think that, obviously, there could be some differences to the polypropylene or there may be other things that could be additives to the polypropylene. There are antioxidants that can be added to help with some of these reactions that we are seeing, the chronic inflammatory, the foreign body reactions we have seen.

Those are things, I have a little bit of knowledge and basis of because of my prior experience and, of course, the mesh work. At least on paper, this ProNova or the PVDF sounds enticing. There certainly may be other products out there that I'm not aware of.

Q. Have you reviewed any published medical literature regarding PVDF or ProNova?

A. Just I have seen what Ethicon's documents were.

Q. So no published materials on that?

A. No, I have not.

Q. Do you know what antioxidants are in the Gynemesh PS used in the Prolift device?

A. Do I know what the antioxidants --

Q. Are.

A. No, not off the top of my head.

Q. Do you know what antioxidants are in the old Promesh that's utilized in the Prolift?

A. No, sir.

Q. So when you say the best material available, you don't have a specific material in mind other than PVDF or ProNova?

A. That's the only specific material in mind. I think that if, sitting down with a bunch of people that could make it happen, biomaterials scientists and so forth, I think I could have some knowledgeable input as to some desirable traits, but no, I don't have a specific one in mind. I can tell you what those traits should be, perhaps, but no.

Q. Have you ever done any testing or experiments utilizing PVDF mesh or ProNova mesh?

A. No, sir.

Q. Are there any PVDF meshes on the market that you are aware of?

A. Not that I'm aware of.

Q. Have you checked into that?

A. I have not.

Q. If there are PVDF meshes on the market, would you be interested in using those?

A. I'd be interested in looking into it, absolutely.

Q. But you haven't gone out and looked to see if there are any PVDF meshes on the market?

A. No, my knowledge, once again, has just been, what, six or seven months.

Q. I want to ask you the same questions about the Prolift+M. How would you change that to make it safer? Would it be the same things you discussed with the Prolift?

A. I think so. I think there was more of an inflammatory problem with the monocryl being in there than they anticipated. Also, it needs to be, the other thing with the mesh, it needs to be isotropic, not anisotropic like it is.

Q. What isotropic meshes for treatment of

pelvic organ prolapse are available on the market?

A. I can say that in regards to the Prolift mesh, it is more one-directional there, anisotropic. You want something that has --

Q. What ones are on the market is what I wanted.

A. The Restorelle is more that way than Prolift. But if there is mesh out there that's marketed as such, then the answer is no.

Q. So the Restorelle is more isotropic than Prolift?

A. It is more isotropic, in my opinion.

Q. So you said that Prolift+M mesh has more of an inflammatory response than Gynemesh PS?

A. Especially in the short term because of the monocryl that's in there. It is one of those things, I think, that as I said earlier in the deposition, I think the idea was worth pursuing. I just don't think it should have been pursued on the open market.

Q. So is your alternative design for the Prolift+M, a mesh that has no absorbable component or would it be a mesh with a different absorbable component than the monocryl?

A. Obviously, I don't think monocryl should be it, with the experience that they had. But maybe there's another one that could be done. Once again, you got to rely on your research to point you in the right direction.

Q. But as you sit here today, you don't have a different absorbable component that you would advocate as safer than Prolift+M?

A. No, I do not at this time.

Q. As a practical matter, do you believe there is any single mesh of any type that can be used appropriately for transvaginal implantation to treat pelvic organ prolapse?

A. In other words, is there one that I would use today?

Q. Yes.

A. First of all, as I told you earlier, I think that the decision to use it can't be undertaken lightly. I think there are patients where it may be appropriate.

Having said that, the ones that I have used most recently was Elevate there. One of the big key differences there that it had was that it was not a transobturator approach there. Of the,

Page 2 that one of the reasons you stopped using the Prolift products in 2008 was due to unacceptably high erosion rate, correct?

A. Yes.

Q. What was that erosion rate?

A. It was over ten percent. I had been using, as we discussed earlier, hand-sewn meshes and so forth. And my erosion rate with hand-sewn meshes was down in the three percent range.

And then with this, as I said, I did at minimum 25, and so it was higher than ten percent. And it just got me scared.

Q. There aren't any data that we could look at to verify that that was the rate, is there?

A. No, sir, as we discussed, I have been through three MRs and some of that was PACH.

Q. You also indicated one of the reasons you stopped using Prolift products was that Gynecare did not exercise due diligence in ensuring that implanting physicians were adequately trained.

A. Correct.

Q. Did you feel that you were adequately trained on the Prolift device when you went to that cadaver lab?

A. I did. I had a lot of knowledge. I had been to a fellowship, I had a lot of knowledge of pelvic floor anatomy and surgeries.

I had already been doing the dissection with free-cut mesh, as we discussed. So I felt I had a good, strong foundation and I got device-specific training by one of their preceptors. So yes, I did feel like it.

Q. On Page 3 of your Prolift report you indicate that, "Ethicon marketed its Prolift mesh devices without first obtaining FDA 510(k) clearance and sold the product for more than three years in the United States without governmental permission."

A. Yes.

Q. What was the basis for that statement?

A. That was in the news.

Q. What news story are you referring to?

A. Gosh, it was, I can't remember, was it the Wall Street Journal or Bloomberg or something? I remember, I think, a buddy of mine even said, hey, check out whichever one it was. And I think it was one of the financial things because they were really -- I think it was one of the financials, either Wall Street Journal or Bloomberg, but it was in the news.

Q. So is it your opinion that the Prolift was marketed illegally?

A. I will say that they did not get their -- if they didn't meet the requirements of the FDA, is that not illegal? I don't know.

I know I can't ask you a question, but I don't know the legalese and all that. To me, they didn't do the government requirements.

Q. So is it fair to say since you don't know the legal requirements, that you don't know if Ethicon's marketing of the Prolift was illegal?

A. I can't comment on that. I'd have to let one of you guys say that.

Q. You say you have worked with medical device manufacturers in the development and evaluation of pelvic repair mesh products.

A. Yes.

Q. Is that the TOPAS work that you referred to earlier?

A. I have done TOPAS work, Avaulta; Bard was not only Avaulta but it was also slings. I have done some other work with AMS/Astora. I did not do any with Ethicon. I did not do any Boston -- yes, those were the ones.

Q. What was your role in the design of the Avaulta product?

A. The Avaulta product, when I first got involved with that, their initial Avaulta biosynthetic was in its final stages. And so I was more involved there at the end as, hey, okay, this is the final thing; how does this look; is this going to work good, and so forth.

Now what I call, and a lot of us term, the second generation Avaulta which the trocars were radically changed, the design of the mesh was radically changed, I had a lot more input into that, like at some of these round table sessions as you referred to as well as some cadaver sessions that were geared just to their KOLs, if you will.

Q. Have you ever developed a battery of testing that was to be done on a device during a device's development?

A. No, sir.

Q. When we were talking earlier about your IFU-related opinions of the Prolift and Prolift+M IFUs, are there any standards that you are referencing where I can go and look on the internet look up that particular standard?

A. I don't know a standard, but this is probably a bad analogy, but who is the guy, the famous Supreme Court guy or whoever that says, I know obscenity when I see it? I think I know a good IFU when I see it.

I don't know that there are standards there. I can certainly go on with you at length about what I think should have been in here, as we have already done.

Q. When you say on Page 3 of your Prolift report that, "In designing a pelvic repair mesh product intended to be sold and implanted by physicians like myself, a reasonable device manufacturer must consider and weigh all of the known risks versus the benefits of a particular design as well as all information known to the manufacturer that may bear on the safety and efficacy of the design including the gravity, severity, likelihood and avoidability of the dangers associated with the design."

Did I read that correctly?

A. Yes, sir.

Q. What is the basis for that statement, that those are the things that a reasonable device

manufacturer must do in designing a product?

A. As we were discussing earlier, certainly I think that it's been established that anterior compartment mesh does have a benefit in anatomical success. We have discussed that earlier, and I don't disagree with what it has shown. But my rejoinder to that would be, at what cost. The --

Q. All I am asking is what the standard is. Where did this standard come from that we just read? Is there some standard I can look up on the internet?

A. No, there's no standard. That's just kind of --

Q. Your take?

A. It is common sense stuff. These are things you trust the manufacturer to do their due diligence in bringing the design to the market, that these things have been done, addressed the positives and the negatives, and made sure that those equal out or are beneficial.

Q. On Page 4 you talk about your opinion that, "The risks inherent in the design of the Prolift outweigh its benefits for several reasons."

So you did a risk/benefit analysis with

A. No, sir, thank you.

Q. On Pages 14 through 18 of your Prolift report you go through and list a number of things that you think that Ethicon failed to put into the IFU for the Prolift that they should have put into the Prolift; is that fair to say?

A. Correct.

Q. Is it your opinion that the FDA would have allowed Ethicon to include all of these things in the Prolift IFU or Prolift+M IFU to the extent it is applicable to those devices?

A. I think they would have, because there were some changes that I saw in Ethicon's documents where the FDA came back and said, you need to add this, you need to add this, some of it had to do with the risk of the surgery, and there was some that Ethicon just didn't want to do.

So, yes, I feel like some of the risk verbiage that the FDA wanted in the revised IFU, I think, yes, they would have allowed a lot of what I have suggested.

Q. Are there any limits that you are aware of on what the FDA will allow a medical device manufacturer to include in an IFU?

A. No, sir, I'm not aware of any limits.

Q. Do you consider yourself to be an expert in FDA regulations?

A. I do not consider myself to be an expert in FDA regulations.

Q. You are not an expert in the FDA regulatory process for bringing medical devices to market, are you?

A. No, I'm not.

Q. What training have you had with respect to the interpretation of FDA regulations, any?

A. No formal training, no.

Q. Any informal training?

A. Just, once again, since all this litigation and concern started, even starting back where the FDA made their first mesh proclamation back a number of years ago, between that and then my involvement in some of the clinical trials I have been involved with, because I was involved with, as you know, TOPAS, and I was also doing some of the 522 studies for AMS.

Q. Is TOPAS an acronym?

A. Yes, sir, transobturator posterior anal sling.

Q. Through how much of the obturator foramen does the TOPAS point pass?

A. Almost immediately when it traverses the obturator foramen, it dives and goes posteriorly there, so it doesn't really dive into the pelvis like you are thinking like heading into the vagina, it doesn't do that. It immediately, once it passes the bone, it goes south, assuming the patient is sitting on an exam table, it goes posteriorly and then down around the anus and back up.

Q. Does it pass through the obturator internus and externus muscles?

A. Yes, it does.

Q. Have you ever written to the FDA and provided them with your opinion regarding transvaginal mesh kits like the Prolift and Prolift+M?

A. No, I have not.

Q. Have you ever spoken with anyone at the FDA about your opinions regarding the Prolift device or Prolift+M device?

A. No, I have not.

Q. Have you ever had a patient experience a complication following a uterosacral ligament

benefits, like I get to use PubMed and I get to do things of that sort, I get some research, someone can research something for me.

Q. You get to put it on your CV?

A. Right.

Q. Does the Medical College of Georgia know that you are serving as an expert on behalf of the Plaintiffs in this litigation?

A. I don't know. I don't necessarily think so.

Q. Are you an expert in determining corporate motive, knowledge or intent?

A. I would say no.

Q. When did you become an expert on the Prolift+M device?

A. I think -- when I was retained? What's the exact question?

Q. You are testifying here as an expert on the Prolift+M device?

A. Yes, sir.

Q. When did you become that?

A. I feel like in general I'm an expert in mesh and I'm an expert in the surgeries required. I guess, I think I would consider myself more of an

expert on mesh in general in the pelvis and the use of mesh in general. I haven't really thought about it as I'm an expert just on one particular one with the exception being, of course, I now have in the last several months have learned a lot of very specific things about the Prolift.

I hadn't thought about the question that way.

Q. Have you ever drafted an IFU for a surgical implant for a medical device manufacturer?

A. No.

Q. Have you ever drafted the warning that accompanied an implantable medical device for a medical device manufacturer?

A. No, sir.

Q. Is it fair to say you don't know what processes are followed for preparing medical device warnings?

A. I don't know what the FDA's thoughts are on that matter, no.

Q. Is it fair to say you don't know the regulations governing medical device warnings?

A. I do not know, no.

Q. Have you ever drafted a patient brochure

for a surgical implantable device?

A. No, sir.

Q. You are not an expert in the design of medical devices, are you?

A. No, sir.

Q. You are not an expert in the design of clinical trials or testing of medical devices, are you?

A. No, sir.

Q. You don't hold yourself out to the community as a warnings expert, do you?

A. No, sir.

Q. Have you had any human factors training or education?

A. What?

Q. Human factors training or education.

A. What is that?

Q. Any training regarding how people interact with warnings and perceive and react to that information, things like that.

A. I would say yes and no. As far as taking a class or something, no. But one of the issues that I was involved with, I think we had to take an online course that dealt with something to that

effect. So I guess I'm somewhat familiar with that.

Q. You are not a pathologist, correct?

A. Correct.

Q. You are not a materials scientist?

A. Correct.

Q. Have you ever participated in an animal study evaluating polypropylene mesh?

A. No, sir.

Q. Have you ever done any lab or benchtop testing on polypropylene mesh?

A. No, sir.

Q. Have you ever done any biomechanical testing of any polypropylene mesh?

A. I don't know if this would qualify. To me partly it would. As I said, back when I was doing work with Bard, we used to -- we would do cadaver courses and so forth.

I'm not talking about to train other physicians, but where we would look at different meshes or anchorings and we would study pullout strength and that sort of thing. So that might qualify partially, to answer your question.

Q. Do you know what the weight of the Prolift mesh is?

A. Still do.

Q. When you assess a woman's progress in labor by determining cervical dilation, do you do that by palpating the cervix?

A. Digitalization, yes, we do a vaginal exam.

Q. Digital meaning your fingers?

A. We put our fingers in, yes, sir.

Q. Did you review any of Ethicon's design protocols for the Prolift or Prolift+M devices?

A. Design protocols, I reviewed a lot of what they had. I don't know what part of it was a design protocol or not.

Q. How did you decide what materials to cite in the end notes of your report or the footnotes of your reports?

A. As the report was unfolding and I was writing it and revising it and revising it and writing it and revising it, I had all the documents around. And it took a while to do, because I would have to go back and find things.

But basically, I have a locked room at my other office where I keep all the stuff, and that's where I go to write on it. So it's all right there at my fingertips.

Q. You have a locked room at your office where you keep the stuff that you have produced here today?

A. Yes, sir.

Q. Any other stuff?

A. Any other stuff?

Q. In that locked room regarding your file materials for these cases?

A. Just things that are with this ongoing litigation or whatever. I'm sorry, I don't understand your question.

Q. I want to understand if there are any file materials that you utilized in forming your opinions regarding the Prolift and Prolift+M products that are back in that locked room in your office that aren't here today.

A. Oh, no, no, sir. I'm sorry.

Q. You say at the bottom of Page 21 of your Prolift report that, "Based upon the current literature regarding armed TVM kits and the articles and abstracts regarding the Gynemesh PS and Prolift products, upon what I have observed when I have removed Prolift mesh, and upon what I have learned from my review of Ethicon's internal documents and

testimony, it is my opinion that the risks of implanting the Prolift far outweighed any perceived benefits with unacceptable rates of mesh exposures, erosions, dyspareunia, urinary and bowel problems, chronic or permanent pelvic pain, painful mesh shrinkage, revisions and reoperations in an attempt to address these complications and recurrences of prolapse following mesh removal surgeries."

Did I read that correctly?

A. Yes, you did.

Q. When you refer to unacceptable rates of those various complications listed there, do you have in mind what an acceptable rate of mesh exposure is?

A. When I was doing my hand-sewn ones, mine was at three percent or less. So for exposure, to have an exposure is not my -- it can be very annoying and concerning to the patient, but if that's the solitary thing, I can fix that. It's these other issues that are a bit concerning.

Q. So a three percent exposure rate is okay with you?

A. That would be ideally even less. My sling exposure rate is less than one.

Q. When you say sling, what do you mean?

A. Once again, a sling is polypropylene mesh. When we first started out, there were people that were having erosion rates of five to seven percent. Mine for the last several years has been like 0.4 percent there.

Q. Understandably, you want the rate to be as low as possible.

A. Absolutely.

Q. But is a five percent exposure rate acceptable to you?

A. I guess if it delivered as promised and there was none of these other complications, I could probably live with that.

Q. Do you use TVT slings?

A. I don't.

Q. How do you treat stress urinary incontinence?

A. I don't use the TVT brand. I use others slings.

Q. What slings do you use?

A. I use, recently I have used Altus, which is a Coloplast sling. I have used, Desara, I think is it D-E-S-A-R-A, which is by Caldera.

I have used Sparc, S-P-A-R-C, which is by AMS, but now will be going off the market there.

Q. All polypropylene slings?

A. All polypropylene.

Q. What's an acceptable rate of erosions for you?

A. I would say the same. I'd like it, I mean, erosion and exposure, I'm sorry, in my mind I kind of lump them in because they are in the vagina.

Q. Five percent would be okay?

A. Or less, yes, as low as possible.

Q. What's an acceptable dyspareunia rate for you in a pelvic organ prolapse repair?

A. Zero.

Q. One percent is unacceptable?

A. No, I guess I could live with that. Obviously, it is probably the thing that one patient, if they have severe dyspareunia and previously their sex life was good, it is a horrible thing to take care of.

Q. The next page, Page 22, you talk about how there were alternative designs available for the Prolift kits, right? We have talked a bit about that today already?

A. Yes, sir.

Q. One thing you say there is "introduction of stress shielding to prevent pore collapse."

What do you mean by that?

A. What stress shielding is referring to in this sentence there is that material that you put in, it takes the physical forces or the stress off the surrounding tissues. You certainly have to be careful with the terminology because, and in the long term, you don't want stress shielding to necessarily be there, because if you remember the Moalli study we discussed, it was felt that some of the vaginal degeneration that was seen with the Prolift mesh was due in fact to stress shielding.

Now, in my mind, I may have this wrong, but in my mind, stress shielding, the way I meant the connotation here is, you want it there in a way to protect the pore size to keep the mesh lying flat, to keep the mesh pores open such that ingrowth can occur. Once that occurs, the stress shielding ideally could wither away or go away.

Q. Does abdominally placed polypropylene mesh degrade, in your opinion?

A. Yes.

Q. Do you believe that Proline sutures degrade?

A. Yes.

Q. On Page 22 at the bottom of the page you say, "I personally observed and treated patients who have been implanted with Ethicon Prolift products that experienced the following device-related complications." And then on the next page you say that, "Those are directly attributable to the defective design of these products as described previously."

Right?

A. Yes.

Q. What design defect in the Prolift and Prolift+M devices causes chronic or permanent pelvic pain?

A. That had to do with the armed nature of the mesh which we have discussed as well as the chronic and ongoing inflammatory/foreign body response induced by the degrading polypropylene mesh.

Q. Anything else?

A. I think that the other thing is poor surgeon training.

Q. Have you ever developed a training course for surgeons to go through in preparation for using a medical device for the first time?

A. No. I've taught some very small ones and I was given kind of free reign to do what I wanted, but no, I don't think I built it from the ground up.

Q. What design defect causes chronic or permanent inflammation of tissues surrounding mesh?

A. That's going to be the degradation of the polypropylene.

Q. Anything else?

A. That's the main thing.

Q. What defect in the Prolift or Prolift+M devices causes excessive scar plate formation, scar banding and contracture of mesh arms? I will leave it at that.

A. Sir?

Q. I'll leave it at that.

A. One, that's going to be your adequate or inadequate pore size once the mesh is placed. You want the mesh to maintain its pore size until the ingrowth occurs.

That is where you are going to get your bridging, your bridging fibrosis which is going to

lead to your scar banding. When you are talking about the arms, then that has to do with the curvature of the arms and basically the mesh arms end up by curving and overlapping themselves. That doubles your mesh density which is going to cause excessive scar plate formation.

Q. What defect in the Prolift or Prolift+M devices causes erosion of mesh into the bladder and rectum and exposure of mesh into the vagina?

A. Once again, obviously, you can't say something like that without commenting on surgical training and surgical technique. But then once again, in something like that where you basically have created like a fistula-type track, inflammation and chronic inflammation is a key point.

Q. What defect in the Prolift and Prolift+M devices, design defect, that is, causes pudendal neuralgia?

A. That can be many things. Number one, it can be the technique itself of passing these trocars blindly. I believe it was the posterior pass that advocated going through the sacrospinous ligament where traumatically the pudendal nerve would be the most at risk of being ensnared in the resultant mesh

arm or lacerated by the tip of the trocar.

Additionally, it has been well-described in the literature the fibrosis around such, how it can affect the surrounding nerves. And nerves can end up getting entrapped or encapsulated in the ongoing fibrotic response.

So it can be the actual technique itself, whether it's from a poor design by a manufacturer or the execution of that by the surgeon. But also, once again, the chronic inflammation is going to play a role in this.

Q. What is the generally accepted method for measuring pore size or porosity in mesh?

A. I believe, if I'm not mistaken, that is with a SEM scan, scanning electron microscopy, I believe. I don't think it is TDM, I think it is scanning electron microscopy.

Q. Can you hold a ruler up to the mesh to measure the pore size?

A. Wait a minute, we are talking about the macro picture, the mesh is laying there, that type of thing.

Q. Yes.

A. Yes, you can do that. I forgot what

amount of force if any is put on it, but yes, you can do that. I was thinking about microscopically.

Q. Have you ever taken a piece of Gynemesh PS or ULTRAPRO mesh and laid it next to a ruler and measured how big the pores are?

A. No.

Q. What's the design defect in the Prolift or Prolift+M devices that in your opinion causes pelvic floor muscle spasms?

A. Once again, the chronic inflammation; the passage of these arms through the various muscles that are present; as well as the irritation and inflammation of the nerves. Once these nerves -- this has been well-described -- are chronically irritated, their threshold for wanting to fire is actually lowered dramatically.

So then things that might otherwise stimulate a pelvic floor muscle contraction -- excuse me, things that otherwise would not stimulate a pelvic floor muscle spasm are now stimulating them. It may just be activities of daily life.

Q. How much farther away does the TOPAS sling traverse from the pudendal nerve than the Prolift?

A. Gosh, it is like the equivalent from here

to California. It is not even in the ballpark.

Q. How many centimeters?

A. Gosh, six, seven, eight, nine.

Q. What's that based on?

A. Just knowledge of anatomy. It's nowhere close.

Q. Is there a cadaver study that's been done that shows that difference?

A. I think if I can show you on a skeleton, you would see it is not even in the same neighborhood.

Q. What is the design defect in the Prolift or Prolift+M devices that causes nerve damage and dyspareunia?

A. Once again, that is, the nerve damage can be many ways. One, it can be the passage -- once again, I guess now we are not talking about pudendal nerve anymore, we are talking about nerves in general here, just to be clear.

So nerve damage as you get excessive fibrosis or scarification, numerous pathology studies have shown that they found nerve fibers in this. So the nerves can get caught up in this ongoing severe scarification is going to be a result

of the healing as well as the chronic ongoing inflammation. Scarification, once again, obviously we said earlier in this deposition, is a good thing for healing, but at some point it needs to quit.

Q. Is there a standardized weight classification system for mesh?

A. Standardized weight, like if it is 20 micrograms, it is low weight; if it is 30 micrograms it is --

Q. Right.

A. I don't know that it is standardized.

Q. So there is no standardized weight classification system that you know of for mesh?

A. Not right off. I think it is one of those things, you kind of know it when you see it.

Q. Do you agree that with any implant in any part of the body, there's the possibility of a chronic foreign body reaction?

A. I think that's a very fair statement.

Q. Not every chronic foreign body reaction leads to pain; is that fair?

A. That's correct.

Q. Recurrence of prolapse is a possibility with any pelvic organ prolapse procedure, correct?

A. Yes, sir.

Q. Just because recurrence of prolapse is possible with a pelvic organ prolapse procedure doesn't mean that procedure or device is defective, does it?

A. Yes and no. So, for example, if the prolapse recurred because of a problem with the device that you had to go in and required its removal, I attribute that to the device.

Q. What is the alleged design defect with the Prolift or Prolift+M devices that you think causes stress urinary incontinence, urge incontinence or urinary retention?

A. I think you have to break those down carefully. Urinary retention is probably going to be twofold. One is going to be perhaps related to the dissection or improper dissection required, even though I will say I found it interesting that there was an email in Ethicon's stuff from David Robinson regarding a couple of patients that he was made aware of that had urinary retention, and both of these patients were operated on by what I intimated to be KOLs. One of them was Dennis Miller there.

It seemed to be prolonged and ongoing and

and ongoing and ongoing after several weeks. So it raises a question of, is that related to the actual passage of the arms and digging up some of the nerves and so forth.

As far as the stress urinary incontinence goes, I think some of that has to do with, once again, with the training there. The urge incontinence is going to be more related to the chronic irritation and inflammation going on and lowering the threshold for the nerves to fire.

Q. I added up on your invoices that we have marked as Exhibit 6 the total amounts reflected on those invoices. That amount was $90,375. Does that sound about right in terms of the amount you have been paid or have invoiced for your work in the pelvic mesh litigation involving Ethicon?

A. It sounds about right, yes, sir.

Q. How much have you earned to date from your work as an expert witness in all of the transvaginal mesh litigation combined, not just limiting it to Ethicon?

A. $250,000. I don't know. With this 90,000 that you just mentioned and what I have done before, it's probably at least 250.

Q. You earn $4,000 for a half day of trial testimony and $8,000 for a full day?

A. Yes, sir.

Q. For your deposition time, you earn $600 per hour with a minimum four-hour charge?

A. Yes, sir.

Q. For travel time to the deposition, you earn $200 in 30-minute increments?

A. Yes, sir.

Q. So if it goes 36 minutes, you would charge $400 for that hour of travel?

A. Yes, sir. I think the first hour I probably would do just 200 and after that -- I'm sorry, I'm getting confused now.

Q. When you travel to testify at a trial for Mr. Hill's firm, the Blasingame firm, how do you get there?

A. I have flown.

Q. Did you fly commercial or on a private plane or jet?

A. It's private.

Q. Did you ever fly in a commercial plane or jet to get to a trial involving the Blasingame firm?

A. No, sir.

C E R T I F I C A T E

G E O R G I A:

HENRY COUNTY:

I hereby certify that the foregoing deposition was reported, as stated in the caption, and the questions and answers thereto were reduced to the written page under my direction; that the foregoing pages 1 through 245 represent a true and correct transcript of the evidence given. I further certify that I am not in any way financially interested in the result of said case.

Pursuant to Rules and Regulations of the Board of Court Reporting of the Judicial Council of Georgia, I make the following disclosure:

I am a Georgia Certified Court Reporter. I am here as an independent contractor for Golkow Global Litigation Services.

I was contacted by the offices of Golkow Global Litigation Services to provide court reporting services for this deposition. I will not be taking this deposition under any contract that is prohibited by O.C.G.A. 15-14-37 (a) or (b).

I have no written contract to provide reporting services with any party to the case, any counsel in the case, or any reporter or reporting agency from whom a referral might have been made to cover this deposition. I will charge my usual and customary rates to all parties in the case.

This, the 20th day of April, 2016.

Maxyne Bursky

MAXYNE BURSKY, CCR-2547